IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
Civil No. 11-CV-1433 (DSD/JJG)

UNITED STATES OF AMERICA,	)
	)
Plaintiff,	)
	)
v.	)
	)
39 cases, more or less, each case containing 72/100 capsule plastic bottles of an article of drug labeled in part:	)
	)
(case and bottle)	)
	)
"*** DDS *** PROBIOTICS *** DDS®-100 (or "DDS® Plus," or "Probioplus DDS®") *** *L. acidophilus DDS-1* *** 100 VEG. CAPS *** UAS LABORATORIES *** Eden Prairie, MN ***"	)
	)
and	)
	)
5 cases, more or less, each case containing 72/2.5 ounce plastic bottles of powder, an article of drug, labeled in part:	)
	)
(case and bottle)	)
	)
"*** DDS *** PROBIOTICS *** DDS® *** Acidophilus *** *L. acidophilus DDS-1* *** 2.5 oz. POWDER *** UAS LABORATORIES *** Eden Prairie, MN ***"	)
	)
and	)
	)
15 cases, more or less, each case containing 72/2.5 ounce plastic bottles of powder, an article of drug, labeled in part:	)

)
(case and bottle))
)
"*** DDS *** PROBIOTICS *** DDS® Plus)
(or "DDS® Junior")*** *L. acidophilus*)
DDS-1 *** 2.5 oz. POWDER *** UAS)
LABORATORIES *** Eden Prairie, MN ***")
)
and)
)
6 cases, more or less, each case)
containing 72/100 tablet plastic)
bottles of an article of drug labeled)
in part:)
)
(case and bottle))
)
"*** DDS *** PROBIOTICS *** DDS® ***)
Acidophilus *** *L. acidophilus DDS-1*)
*** 100 TABLETS *** UAS)
LABORATORIES *** Eden Prairie, MN ***")
)
and)
)
17 cases, more or less, each case)
containing 72/60 capsule plastic)
bottles of an article of drug labeled)
in part:)
)
(case and bottle))
)
"*** CRAN-GYN DDS® *** *DDS®-Probiotics*)
*** 60 VEGETARIAN CAPSULES *** UAS)
LABORATORIES *** Eden Prairie, MN ***")
)
and)
)
all other articles of drug, in any)
form (capsules, powder, or tablets),)
and in any size and type container,)
which are labeled or otherwise)

identified as DDS Probiotics, located on the premises of UAS Laboratories, Inc., 9953 Valley View Road, Eden Prairie, Minnesota,	)
Defendants.	)

CONSENT DECREE OF CONDEMNATION AND INJUNCTION

The United States of America, by and through its attorneys, filed a Verified Complaint for Forfeiture *In Rem* ("Complaint") against the above-captioned articles ("the Defendant Articles") on June 1, 2011.

The Complaint alleges that the Defendant Articles proceeded against are drugs within the meaning of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 321(g)(1)(B), because their labeling, including information on UAS Laboratories, Inc.'s website and links on UAS Laboratories, Inc.'s website, establish that they are intended to be used in the cure, mitigation, treatment, and prevention of disease in man. The Complaint also alleges that the Defendant Articles may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 355(a), because they are new drugs within the meaning of 21 U.S.C. § 321(p) and there are no approvals of applications filed with the United States Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(b) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) in effect for such drugs. The Complaint also alleges that the Defendant Articles are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 352(f)(1),

because their labeling fails to bear adequate directions for use, a requirement from which they are not exempt under 21 C.F.R. § 201.115 because they are unapproved new drugs. By reason of the foregoing, the Complaint alleges that the Defendant Articles are illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

Pursuant to a Warrant for Arrest *In Rem* issued by this Court on June 1, 2011, the United States Marshal for the District of Minnesota ("U.S. Marshal") seized the Defendant Articles on June 2, 2011. Thereafter, the United States caused notice of the Complaint and seizure to be published in accordance with the applicable rules of this Court and Rule G of the Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeiture Actions of the Federal Rules of Civil Procedure.

On June 6, 2011, UAS Laboratories, Inc. ("Claimant"), through its attorneys, intervened and filed a Verified Claim to the Defendant Articles and an Answer to the Complaint. No other party has filed a claim to the Defendant Articles.

WHEREAS Claimant, having appeared and voluntarily consented to the entry of this Decree under 21 U.S.C. § 334(d) without contest, without admitting or denying the allegations in the Complaint, before any testimony has been taken, and waiving the filing and service of an amended complaint seeking injunctive relief, and the United States having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has jurisdiction over the subject matter herein and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334. Venue is proper in this district under 28 U.S.C. §§ 1391(b)-(c) and 1395.

2. Claimant affirms that it is the sole owner of the Defendant Articles and that no other person has an interest in the Defendant Articles. Claimant agrees that it will indemnify and hold the United States harmless should any party or parties hereafter file or seek to file a claim to intervene in this action, or seek to defend or to obtain any part of the Defendant Articles.

3. The seized articles are drugs that are misbranded, as alleged in the Complaint.

4. The seized articles, therefore, are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Claimant shall, pursuant to 21 U.S.C. § 334(e), pay to the United States all court costs, service fees, storage costs, and other proper expenses of this proceeding incurred to date, and such further expenses, costs, and fees that may be incurred and taxed pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within ten (10) calendar days after receiving notice from the United States Food and Drug Administration ("FDA") of such costs.

6. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) calendar days from the date of entry of this Decree, Claimant shall execute and file with the Clerk of this Court a good and sufficient bond with surety in the amount of $200,000.00 (the "Bond"). The

Bond shall be in a form acceptable to the Clerk of this Court and payable to the United States of America, and conditioned on Claimant's abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding.

7. After paying the costs pursuant to paragraph 5 and posting the Bond pursuant to paragraph 6, Claimant shall give written notice to FDA, that Claimant, at its own expense, is prepared to attempt to bring the Defendant Articles into compliance with the law under the supervision of a duly authorized FDA representative ("FDA representative").

8. Claimant shall not commence, permit any other person to commence, or cause any other person to commence attempting to bring the Defendant Articles into compliance with the law unless and until Claimant has submitted to the FDA representative a written statement detailing a proposed plan to achieve such compliance ("Reconditioning Plan") and has received from the FDA representative written authorization to commence implementing such Reconditioning Plan. Such Reconditioning Plan shall require, but not be limited to, ceasing the distribution, through all means, whether directly or indirectly, of claims that the Defendant Articles, or their component ingredients, are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and which cause them to be drugs, pursuant to 21 U.S.C. § 321(g)(1)(B). Within seven (7) calendar days of entry of this Decree, FDA will review the Reconditioning Plan and provide a written notice approving the Reconditioning Plan or a written notice disapproving the Reconditioning Plan and a

written explanation of its deficiencies. If FDA requires that Claimant resubmit the Reconditioning Plan to show correction of the identified deficiencies, Claimant shall submit a corrected Reconditioning Plan to FDA within seven (7) calendar days of receipt of the notice disapproving the Reconditioning Plan. Within fourteen (14) calendar days of receipt of each corrected Reconditioning Plan, FDA will review the corrected Reconditioning Plan and provide a written notice approving the corrected Reconditioning Plan or a written notice disapproving the corrected Reconditioning Plan and a written explanation of its deficiencies.

9. Until the Defendant Articles have been released in writing by the FDA representative for shipment, sale, or other disposition, the U.S. Marshal for this District shall retain custody of the Defendant Articles.

10. Claimant shall at no time, and under no circumstances whatsoever, directly or indirectly, cause or permit the shipment, sale, offer for sale, or other disposal of any part of the Defendant Articles until FDA has released, in writing, all of the Defendant Articles for shipment, sale, or other disposition.

11. The U.S. Marshal, upon receiving notice from FDA in writing that Claimant is authorized to commence bringing the Defendant Articles into compliance with the law, shall release the Defendant Articles from his custody to the custody of Claimant for the sole purpose of attempting to bring the Defendant Articles into compliance with the law pursuant to the approved Reconditioning Plan described in paragraph 8.

12. If an FDA representative has provided a written release of the Defendant Articles for shipment, sale, or other disposition, Claimant's subsequent shipment, sale, or disposal of the Defendant Articles, or any part of them, shall not be performed in a manner contrary to the provisions of the Act or of the laws of any State or Territory (as defined in the Act, 21 U.S.C. § 321(a)(1)-(2)) in which the Defendant Articles are disposed of or sold.

13. If requested by an FDA representative, Claimant shall furnish duplicate copies of invoices of sale of the released Defendant Articles, or such other evidence of disposition as the FDA representative may request.

14. Within forty-five (45) calendar days of receiving written authorization to commence reconditioning, Claimant shall either complete its attempt to bring the Defendant Articles into compliance with the law, in accordance with the approved Reconditioning Plan described in paragraph 8, or destroy the Defendant Articles. The FDA representative's decision regarding the adequacy of Claimant's attempt to bring the Defendant Articles into compliance with the law shall be final.

15. The United States Attorney, upon being advised by an FDA representative that the Defendant Articles have been brought into compliance with the Act and the requirements of this Decree, or destroyed in compliance with this Decree, and that Claimant has paid all costs submitted to Claimant as of that date, will transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be returned to the Claimant.

16. If Claimant does not avail itself of the opportunity to bring the Defendant Articles into compliance or destroy them in the manner stated, the U.S. Marshal shall retain custody of the Defendant Articles, pending an order by this Court regarding their disposition. In the event that it becomes necessary for the U.S. Marshal to retain custody of the Defendant Articles pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

17. If Claimant breaches any condition of this Decree, or in any subsequent decree or order issued in this proceeding, prior to successfully bringing the Defendant Articles into compliance with the law or disposing of the Defendant Articles as set forth in paragraph 14, Claimant shall, at its own expense, immediately return the Defendant Articles to the U.S. Marshal, or otherwise dispose of them pursuant to an order of this Court. In the event that return of any of the Defendant Articles becomes necessary pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

18. Should Claimant fail to abide by and perform all the terms and conditions of this Decree, or any such further order or decree as may be entered in this proceeding, then the Bond shall, on motion of the United States in this proceeding, be forfeited in its entirety to the United States and judgment entered thereon, and any Defendant Articles remaining in the custody of the U.S. Marshal shall be forfeited and disposed of pursuant to further order of this Court.

19. Immediately upon entry of this Decree, Claimant and each and all of its directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, or manufacturing, processing, packing, promoting, or labeling any new drug that claims or represents, directly or indirectly, as being safe and effective for the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, unless and until (a) an approval of an application filed with FDA pursuant to 21 U.S.C. § 355(b) authorizing each and every such claim or representation is in effect for each such product, or (b) an acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312, is on file for each such product;

B. Introducing or delivering for introduction into interstate commerce any misbranded drug, within the meaning of 21 U.S.C. § 352; and

C. Misbranding any drug, within the meaning of 21 U.S.C. § 352, which such drug is held for sale after shipment of one or more components in interstate commerce.

20. Within fourteen (14) calendar days of entry of this Decree, Claimant shall retain an independent person or persons (the "Expert"), without personal, financial (other

than the consulting agreement between the parties), or familial ties to Claimant or its employees, who by reason of background, experience, education, and training is qualified to assess Claimant's compliance with the Act, to review the claims Claimant makes for each of its products on its product labels, labeling, promotional material, and any websites owned or controlled by Claimant including, but not limited to websites referenced, linked to, endorsed, or adopted directly or indirectly by Claimant ("Expert Review").

A. At the conclusion of the Expert Review, Claimant shall prepare a written report analyzing whether Claimant is operating in compliance with the Act, and in particular, certify whether Claimant continues to have any claims on its product labels, labeling, promotional materials, websites owned or controlled by Claimant, or in any other media, including, but not limited to websites referenced, linked to, endorsed, or adopted directly or indirectly by Claimant, that cause any of its products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g). The Expert shall submit this report concurrently to FDA and Claimant within twenty (20) calendar days of the entry of this Decree.

B. If the Expert reports any violations of the Act, Claimant shall immediately cease the conduct cited by the Expert and, within seven (7) calendar days of receipt of the report, shall correct all violations. If Claimant believes that it is unable to correct all violations within seven (7) calendar days, Claimant shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does

not exceed twenty (20) calendar days. Claimant shall correct the violations in accordance with its proposed schedule, unless FDA notifies Claimant that a shorter time frame is required.

C. An Expert Review shall be conducted annually for no less than three years after the completion of the initial Expert Review described in this paragraph. Claimant may use the same Expert for each Expert Review conducted.

D. For each annual Expert Review, the Expert shall submit his or her report concurrently to FDA and Claimant within twenty (20) calendar days from the completion of the Expert Review. If the Expert reports any violations of the Act, Claimant shall immediately cease the conduct cited by the Expert and, within seven (7) calendar days of receipt of the report, shall correct all violations. If Claimant believes that it is unable to correct all violations within seven (7) calendar days, Claimant shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does not exceed twenty (20) calendar days. Claimant shall correct the violations cited by the Expert in accordance with its proposed schedule, unless FDA notifies Claimant that a shorter time frame is required.

E. If the Expert does not report any violations of the Act for three consecutive annual Expert Reviews, Claimant may request FDA in writing to discontinue the periodic Expert Reviews.

21. Claimant and each and all of its directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), shall cease and discontinue all promotion, marketing, and distribution of any article of drug, as defined by 21 U.S.C. § 321(g), upon written notice from the District Director, FDA Minneapolis District Office, that such article is a drug that (1) is misbranded within the meaning of 21 U.S.C. § 352, or (2) is a new drug that is not the subject of an approved new drug application. As part of such notification, FDA may order Claimant to recall misbranded and unapproved new drugs already distributed. FDA may order that Claimant take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Claimant and its products into compliance with the Act, applicable regulations, and this Decree, including, but not limited to, requiring that Claimant reimplement or reinstitute any of the requirements of this Decree. Any cessation of operations, recall, or other directive ordered pursuant to this paragraph shall be initiated by Claimant immediately upon receipt of written notice from the District Director. Any cessation of operations as described in this paragraph shall continue until Claimant receives written notice from FDA that Claimant appears to be in compliance with the requirements of the Act.

22. If Claimant disagrees with the terms of an FDA directive as described in paragraph 21 of this Decree, Claimant may appeal to this Court and shall continue to immediately and fully comply with the terms of the directive unless and until the Court

modifies or overturns the directive. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 29.

23. If Claimant fails to comply with any of the provisions of this Decree, Claimant shall pay to the United States of America liquidated damages in the sum of one thousand five hundred dollars ($1,500) for each day the Decree is violated and an additional sum of one thousand five hundred dollars ($1,500) for each violation of the Act, its implementing regulations, and/or this Decree. Claimant understands and agrees that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, criminal or civil penalties based on conduct that may also be the basis for the payment of the liquidated damages.

24. Claimant shall reimburse the United States for costs associated with any inspections (including the supervision of destruction), examinations, evaluations, record reviews, or analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, the rates are $87.57 per hour and fraction thereof per representative for time spent on inspection and supervision other than laboratory and analytical work; $104.96 per hour and fraction thereof per representative for laboratory and analytical work; and $0.51 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published per diem rate, or the equivalent, for the areas in which the inspections are performed, per representative for subsistence expenses, where necessary. In the event

that the standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

25. Duly authorized representatives of FDA shall be permitted, as and when FDA deems necessary and without prior notice, to make inspections of any of Claimant's facilities or of any new location(s) at which Claimant operates, including buildings, equipment, finished and unfinished materials, containers, and labeling; to take photographs and make videotape recordings; to collect samples of any finished or unfinished materials and products, containers, and labeling; and to examine and obtain copies of all records in Claimant's possession or control relating to the promotion, marketing, manufacturing, and distribution of any and all products, and, without prior notice, to take any other measures necessary to monitor and ensure continuous compliance with the terms of this Decree. The costs of all such inspections and sample analyses shall be borne by Claimant at the rates specified in paragraph 24 of this Decree. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

26. All notifications, correspondence, and communications to FDA required by this Decree shall be addressed to the District Director, Minneapolis District Office, United States Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota 55401, and shall reference the civil action number.

27. Claimant shall bear its own costs and attorneys' fees in connection with this action.

28. Should the United States bring, and prevail in, a civil or criminal contempt action to enforce any term of this Decree, Claimant agrees to pay all attorneys' fees and expenses, including travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and analytical and investigational expenses, incurred by the United States in bringing such an action.

29. Claimant shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be authorized or allowed by either party.

30. Claimant shall provide a copy of this Decree, personally or by registered mail, within ten (10) calendar days from the date of entry of the Decree, to each of Claimant's officers, directors, agents, representatives, employees, successors, assigns, and attorneys. Claimant shall also post a copy of this Decree in the employee common areas at each of its facilities as long as it remains in effect. Within fifteen (15) calendar days of the date of entry of this Decree, Claimant shall provide to FDA an affidavit of compliance, stating the facts and manner of compliance with the provisions of this paragraph.

31. Claimant shall notify FDA in writing at least thirty (30) calendar days before any subsequent change in location, ownership, or character of its business, such as reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation or business entity, the creation or dissolution of subsidiaries, or any other change in the corporate or business structure of any newly-formed business entity (including any "doing business as" entity) over which Claimant has any authority, that may affect compliance with this Decree. Claimant shall provide a copy of this Decree to any successor or assignee at least thirty (30) calendar days prior to the assignment or change in ownership and shall furnish FDA with an affidavit of compliance with this provision at least thirty (30) calendar days prior to such assignment or change in ownership. Claimant further shall notify FDA in writing at least thirty (30) calendar days before any change to its website and before Claimant uses or acquires any new websites including, but not limited to websites referenced, linked to, endorsed, or adopted directly or indirectly by Claimant, that may affect compliance with this Decree.

32. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED Dated this 21st day of June, 2011

s/David S. Doty
David S. Doty, Judge
United States District Court

We hereby consent to entry of the forgoing Consent Decree:

Claimant:

s/ Sitka Dash
SITA K. DASH
President, UAS Laboratories, Inc.
on behalf of UAS Laboratories, Inc.

s/ Ann D. Kennedy
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